DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

August 6, 2014

CardiacAssist, Inc.
Greg Johnson
Director of Regulatory Affairs
240 Alpha Drive
Pittsburgh, PA 15238

Re: K140999
Trade/Device Name: TandemHeart Veno-Venous Cannula Set
Regulation Number: 21 CFR 870.4210
Regulation Name: Cardiopulmonary bypass vascular catheter, cannula or tubing
Regulatory Class: Class II
Product Code: DWF
Dated: May 15, 2014
Received: May 16, 2014

Dear Mr. Johnson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K140999

Device Name
TandemHeart Veno-Venous Cannula

Indications for Use *(Describe)*
The TandemHeart Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

Melissa A. Torres -S

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Section 5
510(k) Summary

Date: 7/22/2014

Applicant

CardiacAssist, Inc.
240 Alpha Drive
Pittsburgh, PA 15238
Telephone: 412-963-7770
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Contact person

Greg Johnson, PhD
Title: Director of Regulatory Affairs
Phone: 412-963-7770 x266
e-mail: gjohnson@tandemheart.com

Device

Trade/Proprietary Name:	TandemHeart Veno-Venous Cannula Set
Common Name:	Veno-Venous Cannula and Introducer
Classification Name:	Cardiopulmonary bypass vascular catheter, cannula, or tubing. (21 CFR 870.4210, Product Code DWF)

Predicate Devices

Avalon (Maquet) Elite Bi-Caval Dual Lumen Catheter (K081820)
TandemHeart Venous Cannula (K133236)

Device Description

The TandemHeart Veno-Venous Cannula Set consists of two components: a 29 Fr. Dual lumen Veno-Venous Cannula and a 13 Fr. Introducer. The Introducer is designed to accept a standard 0.038 inch guidewire. The TandemHeart Veno-Venous Cannula Set is intended as a single patient, single use, sterile device.

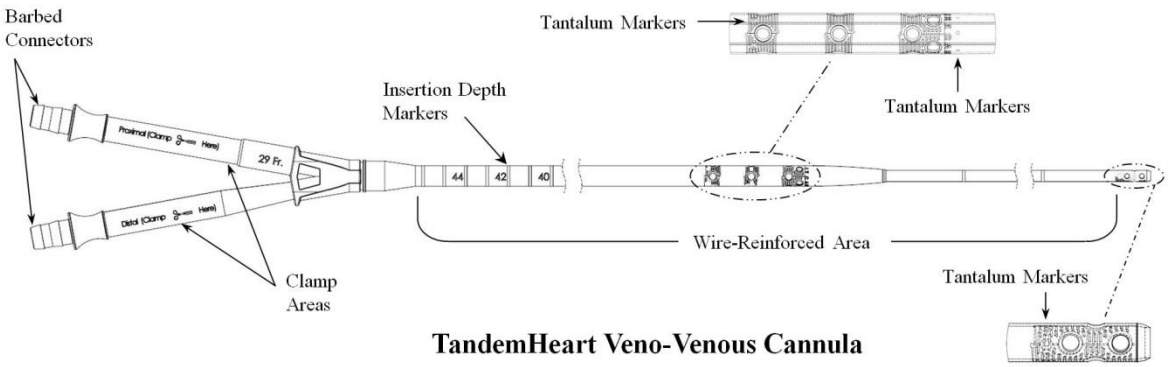

Figure 1. TandemHeart Veno-Venous Cannula

The TandemHeart Veno-Venous Cannula (**Figure 1**) consists of two distinct lumens with a wire-reinforced cannula body. The inner lumen is located entirely within the outer lumen forming two concentric channels

The distal section (inner lumen/cannula) of the cannula body has six side holes near the distal tip opening. The proximal sections of each lumen are clear and not wire-reinforced to allow visualization of blood and to enable clamping to prevent blood flow during set-up and removal of the cannula from the extracorporeal circulatory support equipment (see Figure 1). A non-vented barbed connector is affixed to both proximal ends (inner/distal and outer/proximal lumens) of the cannula and allow for connection of standard 3/8 inch blood circuit tubing for subsequent connection to extracorporeal circulatory support equipment. The cannula has printed insertion depth markings every 10 centimeters from 10 to 30 cm followed by every 2 centimeters for the remainder of the insert-able length, measured from the distal end. The cannula also has a suture wing that can be used for securing the cannula in place to the patient.

The introducer (**Figure 2**) consists of a tube with a hub. The introducer fits inside the inner lumen of the cannula during insertion of the cannula/introducer assembly. The introducer is used to advance the cannula over a guidewire and facilitate cannula placement within the target vessel. The introducer has a hub at its proximal end to manage introducer insertion and removal from the cannula. The hemostasis cap minimizes blood loss when the cannula/introducer assembly is inserted into the target vessel. The introducer body is constructed from radiopaque material for visualization under fluoroscopy.

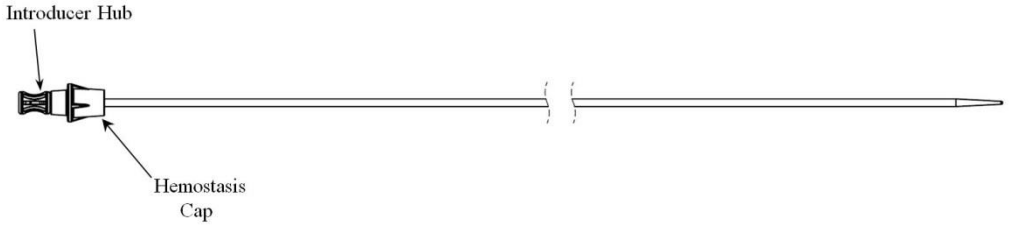

Figure 2: 13 Fr. Introducer

Intended Use

The TandemHeart Veno-Venous Cannula Set is intended for use as a single cannula for both venous drainage and reinfusion of blood via an internal jugular vein during extracorporeal life support procedures.

Comparison of Technological Characteristics

The TandemHeart Veno-Venous Cannula Set and the predicate Avalon (Maquet) Elite Bi-Caval Dual Lumen Catheter (K081820) are both wire–reinforced dual lumen venous cannula. Both kits include an introducer to facilitate placement using a guidewire and fluoroscopy. There are a number of technological differences: 1) the TandemHeart Veno-Venous Cannula Set contains an additional component located on the exterior proximal portion of the cannula: a suture wing to provide a means of securing the cannula to the patient; 2) the TandemHeart Veno-Venous cannula is co-axial whereas the Avalon Elite predicate is bi-caval; 3) the TandemHeart Veno-Venous Cannula has a 29 Fr outer diameter at the proximal end compared to 27 Fr for the comparable Avalon Elite; 4) the TandemHeart Veno-Venous Cannula is longer than the predicate with greater distance between inlet and outlet to reduce recirculation and to allow improved flexibility in positioning within the venous system; and 5) the TandemHeart Veno-Venous Cannula features a taper from the narrow distal, single lumen portion to the larger diameter, proximal, dual lumen portion that is designed to aid with insertion by gradually dilating the vessel.

Performance Data

Non-clinical performance testing was conducted to demonstrate substantial equivalence of flow characteristics between the TandemHeart Veno-Venous Cannula and the predicate, Medtronic Avalon Elite The performance testing included in-vitro system capacity testing and flow vs. pressure drop (HQ). This testing verified that despite the longer length of the TandemHeart Veno-Venous Cannula relative to the Avalon Elite Cannula, it was able to sustain flows comparable to the predicate.

Flexibility, strength, biocompatibility, in-vitro hemolysis, leak testing, sterilization, and shelf life of the TandemHeart Veno-Venous Cannula are addressed by comparison with both the Avalon elite and a second predicate, the TandemHeart Venous Cannula (K133236). Based on the performance test results and data from the predicate devices, the TandemHeart Veno-Venous Cannula was found to meet established design input requirements and thus to be substantially equivalent to the predicate Avalon Elite Dual Lumen Veno-Venous Cannula.